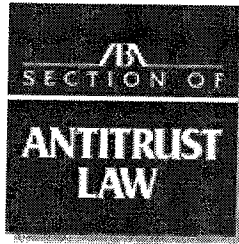


EXHIBIT 3



ECONOMICS COMMITTEE NEWSLETTER

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Economics Committee Newsletter

Welcome

It is with great pleasure that we welcome you to the Fall 2007 volume of our newsletter. The goal of this endeavor is to provide a forum where Antitrust Section and Economics Committee members can share their views on the many faceted relationship between antitrust law and economics.

This newsletter is intended to provoke discussion. As a result, the opinions expressed in this newsletter are only those of the authors. The opinions found herein do not necessarily reflect those of the economics editor, legal editor, their respective employers, or members of the Economics Committee.

Enjoy!

Sincerely,

Seth Sacher, Economics Editor

Neil Imus, Legal Editor

Call for Articles

We are always looking for articles for future issues of the newsletter. If you have an article or an idea for an article regarding the current or improved use of economics in analyzing issues of antitrust law, by all means, please share it with us. Contact Seth Sacher at sethsacher@gmail.com or Neil Imus at nimus@velaw.com for more information.

Economics Committee Newsletter

Calendar of Events

Meet Michael Baye

New Director of the Bureau of Economics at the FTC

October 17, 2007, 12:00PM-1:30PM

Michael will be speaking on "Getting the Most from Your Economic Expert"

Kirkland & Ellis

655 15th Street, NW

RSVP to Connie Carrol, LECG, ccarrol@lecg.com, 202-973-0533. (Your name is needed for security clearance.)

More information is available online at:

<http://www.abanet.org/dch/committee.cfm?com=AT308000>.

Economics Fundamentals of Health Care Antitrust

November 8, 2007, 9:00AM-12:30PM

This economics fundamentals for lawyers program will focus on hospitals, health care professionals and health care insurers.

Moderator

Tracey Weir, Hogan & Hartson

Faculty:

David Argue, Economists Incorporated

Lawrence Wu, NERA Economic Consulting

Hogan & Hartson

555 13th Street

Washington, DC

RSVP to Connie Carrol, LECG, ccarrol@lecg.com, 202-973-0533.

Market Definition in Cases Involving Branded and Generic Pharmaceuticals

Robert Lerner and Caterina Nelson*
CRA International

As the term relevant market suggests, market definition does not occur in a vacuum. The analysis underlying market definition must do more than merely investigate whether two or more products compete at all or under some set of circumstances. A properly defined market is one that is relevant to the analysis of the competitive issues arising in a specific scenario and takes account of the nature of the alleged or potential anticompetitive effects being examined.

We develop this argument below, in the context of an antitrust case involving a prescription pharmaceutical: *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.* In this matter, the court was faced with the question of whether a branded drug should be included in the same relevant product market as generic formulations of the drug. CRA was retained by counsel for plaintiffs to determine the relevant market and analyze the competitive impact of defendants' actions.¹ From our analysis, we concluded that the nature of competition between two generic formulations of a branded drug (and the difference between this competition and that between a branded drug and its generic equivalents) was such that the relevant market comprised only the generic products. Plaintiffs lost on summary judgment on the antitrust issues, based in large part on the District Court's opinion that the brand and its generic alternatives were in the same market,² but the Second Circuit reversed the dismissal of the antitrust claims, finding that the relevant market for purposes of the case

was limited to the generic products.³ The parties subsequently settled the litigation.

The Case and Analytical Issues

Although its patent expired in 1962, DuPont remained the sole U.S. supplier of warfarin sodium, an oral anti-coagulant sold under the brand name Coumadin, until 1997, when Barr Laboratories introduced a generic version of the product. Shortly thereafter, a joint venture of two pharmaceutical companies sought to launch a second generic version, but the launch was delayed by approximately a year following FDA approval. The second generic entrant ("Geneva") filed suit, alleging that the delay in its entry was caused by the anticompetitive conduct of Barr and other defendants.

Market definition was a primary and contentious issue in the litigation and was also central to the issue of whether Barr possessed monopoly power. The parties and their economic experts agreed that there was competition between Coumadin and generic warfarin sodium but disagreed vigorously about the relevance of this competition to the issues at hand.⁴ Defendants argued that the relevant market was the molecule, encompassing both Coumadin and its generic equivalents, and that Barr lacked monopoly or market power in that market. The District Court, having determined that the relevant market included both Coumadin and generic warfarin sodium, found that during the period of defendants' alleged anticompetitive behavior, "Barr's share of the relevant market ... grew from 11% to 14%, [that] as of December 2000, Barr's share was about 24%, [and that] [t]hese percentages cannot support a claim for monopolization or attempted monopolization."⁵

In our view, the nature of the competition between the branded and generic versions of warfarin sodium did not warrant the

conclusion that, for purposes of evaluating the competitive issues in this case, the relevant market was the molecule. Competition between Coumadin and generic warfarin sodium differed in fundamental respects from competition between two or more suppliers of the generic product. While Coumadin's price set a ceiling on the price Barr could charge, it was competition between Barr and Geneva that would determine how close the generic price came to this ceiling. The relationship between Barr's and Coumadin's prices was irrelevant to the issues in the case, moreover, because the alleged anticompetitive effect was that Barr's conduct enabled it to extend the time it was able to maintain its price at this ceiling.

More generally, the proper antitrust market in a case is the market relevant to an analysis of the competitive effects of the alleged behavior. For example, if the allegation is that a manufacturer of a therapeutically unique brand-name prescription drug has engaged in exclusionary behavior to prevent or delay entry by the first generic supplier of the drug, the proper market for evaluating the competitive effects of such conduct is likely the molecule, because the alleged anticompetitive effect is suppression of competition between the brand and the generic.⁶ On the other hand, if the allegation under investigation is that the sole generic supplier of a pharmaceutical has engaged in unlawful behavior to prevent or delay entry by a second generic supplier, the relevant market for analyzing the competitive effects of such conduct encompasses only the generic product, as evidenced by the differential impacts of additional generic entry on the prices of the generic and branded products.

In the warfarin sodium case, the delay in additional generic entry had no impact on the price of Coumadin, but it did enable Barr to realize a premium price as the sole supplier

of generic warfarin sodium for approximately an additional year. This conclusion and the underlying analysis are strongly supported by evidence cited by the Second Circuit in its opinion in the case.⁷ Barr introduced its generic product at about 70 percent of the price of Coumadin and maintained this relationship until Geneva entered the market. Geneva's entry had no discernible effect on the price of Coumadin, which continued to rise. In sharp contrast, Geneva's entry had a substantial and immediate impact on Barr's pricing, resulting in a significant decline in the generic price. Evidence supporting this impact on Barr's price can be found in IMS price data, the testimony of Barr executives, Barr's own price forecasts, and its differential pricing of two dosage strengths not offered by Geneva.

The Second Circuit noted the differential impact of additional generic entry: "When other generic competitors entered the market, Barr's prices dropped substantially, but Coumadin's remained unchanged and even rose slightly."⁸ Barr's invoice prices dropped by a small, but statistically significant amount, and, more importantly, competition with Geneva forced it to offer substantial off-invoice discounts and rebates as well. The court cited testimony of Barr's senior vice president of sales and marketing confirming the impact of Geneva's entry on Barr's pricing: "Regarding wholesalers, he testified Barr offered 15-20 percent rebates after Geneva entered, and with chain pharmacies, he confirmed that Geneva's entry cost Barr 'many millions of dollars.' As one example, he noted that Geneva's entry forced Barr to give rebates to the CVS and Walgreens chain pharmacies each in excess of a million dollars a year."⁹ Additional evidence of Barr's market power came from the differential impact of Geneva's entry on Barr's pricing of different dosage strengths of the product. Barr cut the prices of the dosage strengths that Geneva offered, but not of the

two dosage strengths for which Barr remained the sole generic supplier.¹⁰

Barr's planning documents also recognized the distinct nature of its competition with other generic suppliers. Barr forecasted a price for its warfarin sodium equal to 70 percent of Coumadin's price in the first year after its entry, when it was the only generic supplier; 50 percent in the second year, when it assumed a second generic supplier would enter; and 40 percent in the third year, when it assumed a third generic supplier would enter.¹¹ Furthermore, the Court noted: "This effect is consistent with the literature on generic drug competition describing how generic pricing is a function of the number of generic competitors."¹²

In discussing industry recognition of the distinct nature of competition among generics, the Second Circuit cited the testimony in another matter of Dr. Bernard Sherman, then a director of and major stockholder in Barr: "...As a result, from the standpoint of the patentee drug company, it matters not whether there is one, two, ten or twenty generic drug companies since each successive generic entrant only gains market share from the previous generic competitors and not from the patentee."¹³

General Issues

Failure to account for the differences in the nature of competition between a branded pharmaceutical and its generic equivalents and competition among generic products in defining antitrust markets and evaluating the competitive effects of firm behavior is an example of "The Price-Up Trap," which Professor Steven C. Salop defines as "Mistaking a firm's inability to profitably raise price above the current level for an inability to exercise market power by preventing competitors' conduct that would otherwise reduce price below the current

level, thereby labeling a maintenance of market power as a lack of market power."¹⁴

In defining a relevant market in an antitrust case involving two products, it is, of course, necessary to inquire whether the two products compete with each other. An affirmative conclusion does not end the analysis, however, as not all substitutes are the same in the way and to the degree that they constrain the pricing discretion of a particular supplier or group of suppliers. Only after examining the nature and extent of competition involving the two products in the context of the facts in the case and the alleged or potential anticompetitive effects of the behavior under investigation can one complete the process of market definition.¹⁵

* The analysis and conclusions are those of the authors and do not necessarily represent the views of CRA International. We wish to thank Tasneem Chipty and Bob Levinson of CRA, Colin Underwood and Harry Frischer of Proskauer Rose LLP, Michael Gallagher of White & Case LLP, and Fred Dettmer of the Law Office of Frederick R. Dettmer for contributing to our analysis of the case and to this paper.

¹ Larner was the testifying economic expert for plaintiffs and was supported by a team of CRA economists led by Nelson. In compliance with the protective order in the case, we cite only evidence in the public record and not other confidential information and data that we took into account in our analysis.

² 201 F.Supp.2d 236 (S.D.N.Y. 2002). According to the Court, "In order to establish the existence of a submarket consisting solely of the generic sodium warfarin, plaintiffs primarily rely on a supposed price increase on the part of Coumadin(R) and price decrease on the part of Barr's generic product after the plaintiff's entry into the market." (See 201 F.Supp.2d 236 (S.D.N.Y. 2002) at 269, citations omitted.)

³ Geneva Pharmaceuticals Technology Corp., et al. v. Barr Laboratories, Inc. et al., 386 F.3d 485.

⁴ This agreement was noted in the District Court's opinion. (See 201 F.Supp.2d 236 (S.D.N.Y. 2002) at 269.)

⁵ See 201 F.Supp.2d 236 (S.D.N.Y. 2002) at 271.

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⁶ This is the market definition asserted by Barr in its antitrust suit against DuPont Merck, the manufacturer of Coumadin, *Barr Laboratories, Inc. v. DuPont Merck Pharmaceutical Company*.

⁷ As we mention above, the Second Circuit reversed the District Court's dismissal of the antitrust claims, stating that "...the relevant market for our purposes is the market for generic warfarin sodium tablets." (See 386 F.3d 485 at 500.)

⁸ *Id* at 497.

⁹ *Id* at 497.

¹⁰ Barr later cut the prices of these two dosage strengths when another generic competitor began to offer them. While this might be viewed as support for separate markets by dosage strength, our argument was that it was confirmatory evidence of the existence of a generic-only market, as DuPont sold all dosage strengths of Coumadin, yet the only prices that were changed were for the dosage strengths sold by both generic manufacturers.

¹¹ *Id* at 499.

¹² *Id*. Indeed, a 2002 FTC Working Paper looked at the impact of the number of generic firms on the ratio of the generic price to the pre-patent expiration brand price and found that the ratio fell from 82 percent when there was one generic firm to 76 percent when there were two (falling to 71 percent with five firms). (See Reiffen, David, and Michael R. Ward, "Generic Drug Industry Dynamics," FTC Working Paper 248, February 2002, p. 23 and Table 4.) Reiffen & Ward's results are consistent with the findings by Caves, Whinston, and Hurwitz that the ratio of the generic price to the branded price was 7.35 percent higher when there was only one generic product than when there were two generic products. (See Caves, Richard E., Michael D. Whinston, and Mark A. Hurwitz, "Patent Expiration, Entry, and Competition in the U. S. Pharmaceutical Industry," *Brookings Papers: Microeconomics* 1991, pp 1-66, at p. 34.)

¹³ 386 F.3d 485 at 498. The Court also noted that Dr. Sherman was defendant ACIC/Brantford's principal owner.

¹⁴ Salop, Steven C., "The First Principles Approach to Antitrust, Kodak, and Antitrust at the Millennium," 68 *Antitrust Law Journal* pp. 187-202, at p.194.

¹⁵ This analysis of whether there were significant differences in the nature or extent of competitive constraints imposed by different products or suppliers in determining the relevant market was done by the courts in the *Staples* and *Whole Foods* cases. In *Federal Trade Commission v. Staples, Inc. et al.*, 970

F. Supp. 1066, at 1080, the court found that the relevant product market was limited to sale of consumable office supplies through office supplies superstores, because "...non-superstore sellers of office supplies are not able to effectively constrain the superstores' prices....," whereas the court in *Federal Trade Commission v. Whole Foods, Inc., et al.*, 502 F. Supp. 2d.1 at 32 (D.D.C. Aug. 16, 2007) found that the relevant product market was not limited to "premium natural and organic supermarkets," as claimed by the FTC, due to evidence that "many customers could and would readily shift more of their purchases to any of [the] increasingly available substitute sources of natural and organic foods....," which would defeat a small but significant and non-transitory increase in price.